Remarks

This communication is responsive to the office action dated August 08, 2008 and is a reiteration of points made to Examiner during a telephonic interview initiated by Applicants' attorney on November 04, 2008, to better understand the office action dated August 08, 2008. A conclusion was not reached during the interview but applicants' attorney was requested to submit a response reflecting the points made during the interview for consideration.

In the application, Claims 1-4 are pending. Examiner has rejected Claims 1-3 under 35 U.S.C. 102(a) and (e) as being anticipated by Ogletree US 6,509,348 as evidenced by Ekelund et al BMC Emergency Medicine, 2001, 2(1), 12 pages" Examiner has also rejected Claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Asai et al., EP1350511 A1 translated version of WO 02/051412 in view of Mehta et al., The Lancet, vol. 358, 2001 p 527-533 (of record). Further, examiner has opined that "in order to overcome the rejection (obviousness rejection) the showing of unexpected result, the result must be commensurate with claimed invention" (emphasis added).

Applicants provide amended Claims 1-4 inclusive and arguments believed to overcome Examiner's rejection based on 35 U.S.C 102 (a) and (e) and 103(a). The amended claims are designed to bring the claims in line with and commensurate with the unexpected results.

Amendments

Applicants have amended Claim 1 to 4 inclusive to remove the phrase "high risk vascular disease and." Applicants have also replaced the term "comprising" with the phrase "consisting essentially of." Applicants believe amendments to Claims 1 to 4 inclusive and arguments presented herein obviate Examiner's rejections for anticipation and obviousness. Furthermore, applicants believe no new matter has been introduced by operation of claim amendments herein.

102(a) and 102(e) Rejection

Examiner has rejected Claims 1 to 3 inclusive as being anticipated by Ogletree et al as evidenced by Ekelund et al. Applicants believe that the 102(a) and 102(e) rejections are improper because the invention which is the subject of the instant

application was not known, used in this country, or described in a printed publication in this or a foreign country before the invention thereof by applicants.

Examiner's reliance on Ogletree is misplaced because Ogletree specifically teaches the combination of an ADP receptor antagonist and a thromboxane A2 receptor antagonist optionally in combination with a cholesterol lowering agent or aspirin and a method of using said combination. Thus, thromboxane A2 receptor antagonist is a necessary component of the combination.

Ogletree does not teach the use of an ADP platelet aggregator inhibitor or the compound of the present invention (without a thromboxane A2 receptor antagonist) for the treatment of acute coronary syndromes or recurrence thereof in conjunction with percutaneous coronary intervention for a patient in need thereof optionally in combination with aspirin as disclosed and claimed in the instant application.

35 U.S.C. 102(e)

As discussed above, what Ogletree disclosed is the combination of an ADP receptor blocking antiplatelet drug (including clopidogrel, ticlopidine and prasugrel (CS-747)) and a thromboxane A2 receptor antagonist optionally in combination with a cholesterol lowering agent and/or aspirin and the method of inhibiting platelet aggregation and thrombus formation employing such combination. Ogletree did not disclose the use of the compound of the present invention (without a thromboxane A2 receptor antagonist) in combination with aspirin for the treatment of acute coronary syndrome in conjunction with percutaneous coronary intervention as disclosed and claimed in the instant invention.

For the foregoing reasons, including claim amendments made herein, Applicants respectfully request withdrawal of the rejection of Claims 1-3 inclusive on the basis of 35 U.S.C. 102(a) and (e).

35 U.S.C. 103(a) Rejection

Examiner has rejected Claims 1-4 under 35 U.S.C.103(a) as being unpatentable over Asai et al., EP1350511 translated version of WO 02/051412 in view of Mehta et al., The Lancet 358, 2001 p527-533 (of record).

Further, Examiner has opined that "[i]n order for the rejection to be overcome by unexpected result, Applicant must compare the invention against the prior art which is relied upon in the rejection and not any prior art citing Blanchard v. Ooms 68 USPQ 314 91946" (emphasis added).

In response, Applicants submit that Asai discloses the use of the compound of present invention for multiple uses including as a treatment in stent therapy. Specifically, Asai et al discloses:

> "Thus the use of pharmaceutical compositions of compounds of the present invention for the "prevention or treatment of multiple diseases including diseases caused by thrombus or embolisms, for example diseases induced by platelet aggregation, including stable and unstable angina pectoris, and so forth; cardiovascular or cerebrovascular disorders, e.g., thromboembolism, associated with atherosclerosis or diabetes mellitus, such as unstable angina pectoris, cerebral ischemic insult or restenosis due to angioplasty, endarterectomy or stent therapy; or thromboembolism caused by thromboembolization such as recurrent embolism after degradation of the original thrombus, embolism, ischemia-induced dementia, peripheral arteriopathy, thromboembolization in the vascular prosthesis, or in the bypass between the aorta and the coronary artery."

Applicants submit that from the many uses of the compound as disclosed in Asai, one of skill in the art is not apprized of the significant unexpected property of the compound of the present invention. Asai provides teaching, suggestion or reasonable direction to enable one of skill in the art to arrive at the present invention.

Applicants have discovered a unique property of the compound of the present invention which is its unexpectedly superior efficacy compared to clopidogrel, the current clinical standard in the field, for the treatment of acute coronary syndrome in conjunction with percutaneous coronary intervention optionally in combination with aspirin.

Therefore, the above disclosures notwithstanding, Applicants believe the present claims as amended are unobvious due to the discovery of unexpectedly superior results obtained with the compound of formula I in conjunction with PCI in the TIMI TRITON-38 study. The TIMI TRITON-38 study compared prasugrel versus clopidogrel (the compound in the Mehta and Smith references) in a study of 13,608 patients with acute coronary syndromes undergoing PCI. Wiviott et al., in Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes, N. England J. Med. 357(20) 2001 (2007) concluded that "[i]n patients with acute coronary syndromes with scheduled percutaneous coronary intervention, prasugrel (prasugrel is the non-proprietary name for the compound of formula I) therapy was associated with significantly reduced rates of ischemic events, including stent thrombosis, but with an

increased risk of major bleeding, including fatal bleeding" (emphasis added). Specifically, the authors found that:

- the primary efficacy end point occurred in 12.1% of patients receiving clopidogrel and 9.9% of patients receiving prasugrel (hazard ratio for prasugrel vs. clopidogrel, 0.81; 95% confidence interval [CI], 0.73 to 0.90; P<0.001)
- significant reduction in the prasugrel group in the rates of myocardial infarction (9.7% for clopidogrel vs. 7.4% for prasugrel; P<0.001)
- urgent target-vessel revascularization (3.7% vs. 2.5%; P<0.001)
- stent thrombosis (2.4% vs. 1.1%; P<0.001)

Applicants reiterate that the Asai reference provided a list of diseases for which the compound of the present invention was deemed useful. However, the Asai reference singly or in combination with the Mehta reference did not teach, suggest or motivate one of skill in the art or provide a reasonable expectation of the clinically superior outcomes for the compound of formula I compared to clopidogrel in patients with acute coronary syndromes undergoing PCI. Furthermore, such unexpectedly superior results could not have been predicted by one of ordinary skill in the art on the basis of common knowledge.

For all of the above reasons including the amendments herewith, Applicants respectfully request reconsideration of the rejections under 102(a), 102(e) and 103(a).

Respectfully submitted,

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